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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/600,566 10/16/00 PFLAUM

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HM12/1024

EXAMINER

SAUCIER, S

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/600,566

Applicant(s)

Pflaum et al.

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claims 24-46 are pending and are considered on the merits.

Specification

The disclosure is objected to because of the following informalities:

No drawings have been found which were submitted with the original papers; however, the specification refers to drawings under "Detailed Description. All references to Drawings should be canceled.

A new substitute specification should be submitted because of incorrect top margins which have resulted in punching through the text and loss of printed matter at the top of the pages in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112
INDEFINITE

Claims 24-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites in the last step, "from an organic solvent having limited miscibility or solubility with water". However, "limited" is a term of reference without an adequate point from which to compare the "limits" of solubility or miscibility.

Claims 36 and 40 use the same phrase "limited miscibility or solubility".

Claims 24 and 40 also recite that a "water-soluble organic solvent" is used. Please note that, strictly speaking, all organic solvents have some solubility in water. Thus, the metes and bounds of the claim cannot be ascertained.

Insertion of the list of solvents on page 7 or the limits of solubility for both "water soluble" and "limited solubility in water" would overcome this rejection.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 40-42 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,319,039 [AB].

The claims are directed to a process for purifying HMG-CoA reductase inhibitors comprising crystallizing from a water-soluble organic solvent and from an organic solvent which has limited solubility in water.

The references are relied upon as explained below.

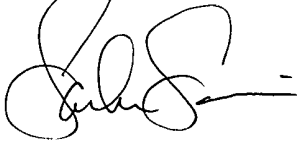
US 4,319,039 discloses a process for purification of HMG-CoA reductase inhibitors comprising crystallizing the ammonium salt of an HMG-CoA reductase inhibitor from a mixture of 50% chloroform, methanol, ammonium hydroxide (80:20:2)/ 50% ether and then recrystallizing from ethanol to yield greater than 90% purity. Alternatively, the ammonium salt of an HMG-CoA reductase inhibitor is dissolved in toluene and crystallized, then recrystallized from ethanol (col. 13, l. 22-45). Please note that the term, greater than 90% purity encompasses the range from 90.1% to 100% which is within applicant's claimed range.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 6:00PM Tuesday-Friday and every other Monday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone

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number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a horizontal line extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
October 10, 2001